

WHAT IS CLAIMED IS:

1. A method of sterilizing a medical device component, comprising applying an electron beam to the component in an evacuated or inert gas-filled container.

5 2. The method of claim 1 including sealing the container so that the container is airtight, after the medical device component is placed therein and before the electron beam is applied.

10 3. The method of claim 2 including purging the container by evacuating the container and filling the evacuated container with inert gas, before the container is sealed.

 4. The method of claim 2 including filling the medical device component with an inert gas, before the container is sealed.

15 5. The method of claim 3 wherein the medical device component is selected from the group consisting of a catheter shaft and a catheter balloon, and including purging the medical device component by evacuating the medical device component and filling the medical device component with an inert gas, before the container is filled with the inert gas.

 6. The method of claim 5 wherein the medical device component is purged before being placed in the container.

20 7. The method of claim 5 wherein the medical device component and the container are purged inside an evacuated or inert gas-filled chamber.

8. The method of claim 7 wherein the container is sealed inside the chamber.

9. The method of claim 1 wherein the electron beam has an energy of about 3 to about 10 MRads.

5 10. The method of claim 9 wherein the electron beam is applied in a single dose of about 2 to about 10 seconds.

11. The method of claim 1 wherein the electron beam is applied in multiple doses, each dose being about 2 to about 10 seconds at an electron beam energy of about 2 to about 5 MRads.

10 12. The method of claim 1 wherein the medical device component is formed of a polymeric material selected from the group consisting of a fluoropolymer, polytetrafluoroethylene, expanded polytetrafluoroethylene, and polyether block amide, and including applying the electron beam at an energy level of about 2 to about 10 MRads.

15 13. A method of sterilizing a catheter balloon, comprising applying an electron beam to the balloon in an air tight, air-free, sealed container.

14. A method of sterilizing a balloon catheter, comprising applying an electron beam to the balloon catheter in an evacuated or inert gas-filled container.

20 15. The method of claim 14 including purging the container with the balloon catheter therein by evacuating the container and filling the evacuated

container with inert gas, and sealing the purged container with the balloon catheter therein, before the electron beam is applied.

16. The method of claim 15 including purging the balloon catheter by evacuating the balloon catheter and filling with inert gas, before the container
5 sealed.

17. The method of claim 16 wherein the balloon catheter is purged before being placed in the container and before the container is purged.

18. The method of claim 16 wherein the container is purged inside an evacuated or inert gas-filled chamber.

10 19. The method of claim 16 wherein the purged container is sealed inside the evacuated or inert gas-filled chamber.

20. The method of claim 15 including mounting a stent on an outer surface of the balloon before the electron beam is applied, and the electron beam is applied to the outer surface of the balloon so that the stent reduces penetration of the
15 electron beam into sections of the balloon located directly underneath the stent.

21. A method of sterilizing a balloon catheter having a balloon on an elongated shaft, comprising

a) purging the balloon catheter by evacuating the balloon catheter and filling the evacuated balloon catheter with an inert gas, and

20 b) applying an electron beam to the purged balloon catheter in an air tight, inert gas-filled container, to sterilize the balloon catheter.

22. The method of claim 21 wherein the balloon has a first rupture pressure before the sterilization and a second rupture pressure after the sterilization, and the electron beam is applied to the purged balloon catheter such that the second rupture pressure of the balloon is not more than about 10% to about 15% less than the first rupture pressure.

23. The method of claim 21 wherein the balloon has a first fatigue resistance before the sterilization and a second fatigue resistance after the sterilization, and the electron beam is applied to the purged balloon catheter such that the second fatigue resistance is not more than about 5% to about 10% less than the first fatigue resistance.

24. A medical device component sterilized by the method of claim 1.

25. A balloon sterilized by the method of claim 13.

26. A balloon catheter sterilized by the method of claim 21.

27. A balloon catheter, comprising an elongated shaft and a balloon mounted on the shaft, sterilized by an electron beam applied to the balloon catheter in an evacuated or inert gas-filled container, so that the balloon has a first rupture pressure before the sterilization, and a second rupture pressure after the sterilization which is not more than about 10% to about 15% less than the first rupture pressure of the balloon.

28. The balloon catheter of claim 27 wherein the second rupture pressure of the balloon is at least about 15 to about 20 atm.

29. The balloon catheter of claim 27 wherein the balloon has a first fatigue resistance before the sterilization and a second fatigue resistance after the sterilization which is not more than about 5% to about 10% less than the first fatigue resistance of the balloon.

5 30. The balloon catheter of claim 27 wherein the balloon has a wall thickness of about 0.01 to about 0.03 mm.

31. The balloon catheter of claim 27 wherein the balloon is formed of a polyether block amide polymeric material.

32. A balloon catheter, comprising an elongated shaft and balloon
10 mounted on the shaft and formed of a polyether block amide, sterilized by an electron beam applied to the balloon catheter in an evacuated or inert gas-filled container, the balloon having a first rupture pressure before the electron beam sterilization, and a second rupture pressure after the electron beam sterilization which is at least about 15 to about 20 atm, and having a wall thickness of about 0.01
15 to about 0.03 mm.